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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,297	03/03/2000	Moon Young Lim	4600-0130.30	5390
22918	7590	05/13/2004	EXAMINER	
PERKINS COIE LLP P.O. BOX 2168 MENLO PARK, CA 94026			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER

1653

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/518,297	Applicant(s) LIM ET AL.	
	Examiner Chih-Min Kam	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 52 and 53 is/are allowed.
- 6) ☒ Claim(s) 40-43, 45, 46, 50, 51 and 54-59 is/are rejected.
- 7) ☒ Claim(s) 44 and 47-49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Claims 40-59 are pending.

Applicants' amendment filed February 17, 2004 is acknowledged, and applicants' response has been fully considered. Claims 6, 9, 10, 12, 18, 19, 21-26 and 34-39 have been cancelled, and new claims 40-59 have been added. Therefore, claims 40-59 are examined.

Objection Withdrawn

2. The previous objection of claims 12 is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 7 in the amendment filed February 17, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claim 6 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 7 in the amendment filed February 17, 2004.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 6, 12, 21-26 and 34-39 under 35 U.S.C. 102(b) as being anticipated by Bujard *et al.* (WO 94/29442), is withdrawn in view of applicants' cancellation of the claim 7 in the amendment filed February 17, 2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 40-43, 45, 46, 50, 51 and 54-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Bujard *et al.* (WO 94/29442).

Bujard *et al.* teaches a system for regulating expression of eucaryotic genes using components of the Tet repressor/operator/inducer system of prokaryotes in a host cell, and transcription of a nucleotide sequence operably linked to at least one tet operator sequence is stimulated by a tetracycline (Tc)-controllable transcriptional activator fusion protein (tTA) which comprises two polypeptides, the first polypeptide is a Tet repressor (TetR), which binds to tet operator sequence in the absence of Tc (claims 54, 55, 58 and 59), and the second polypeptide directly or indirectly activates transcription in eucaryotic cells, e.g., the second polypeptide can be a transcriptional activation domain from herpes simplex virus viron protein 16 (VP16) (page 2, lines 4-14; claims 56 and 57), where in the absence of Tc, transcription of a gene operably linked to a tTA-responsive promoter (typically comprising at least one tet operator sequence and a minimal promoter) is stimulated by a tTA (page 2, lines 17-21). The reference also indicates a host cell can contain a polynucleotide moiety encoding a tTA and a gene of interest operably linked to a tTA-responsive transcriptional promoter, where the gene of interest operably linked to the tTA-responsive transcriptional promoter can be integrated into DNA of the host cell either randomly (e.g., by introduction of an exogenous gene) or at a predetermined location (e.g., by targeting an endogenous gene for homologous recombination, the integration of polynucleotide encoding tTA and a tTA-responsive promoter, page 3, lines 24-39; claims 40, 42, 43, 45, 46, 50 and 51), and expression of a gene of interest operably linked to a tTA-responsive transcriptional promoter in a host cell can be inhibited by contacting the cell with Tc (page 4, line 1-31; page 12, lines 19-37; claim 41). The tTA in the presence of Tc is a DNA binding compound and

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modulates the binding of tTA (a transcriptional regulatory protein) to the DNA response element, which meet the criteria of claim 40.

In response, applicants indicate the Examiner states that “the tTA acts not only as transcriptional regulatory protein but also as a DNA binding compound” in the previous rejection, which appears indicating the previous claims encompass a system in which the transcriptional regulatory protein and a DNA binding compound are the same entity (see also page 3 of 3/27/03 Office Action regarding SREBP-1); the new claim 40 recites “said DNA binding compound, when bound to said binding sequence, is effective to modulate binding of said transcriptional regulatory protein to said DNA response element”, which could not logically include a system in which the transcriptional regulatory protein and a DNA binding compound are the same entity because a compound could not logically modulating binding of itself (pages 7-8 of the response). The response has been fully considered, however, the argument is not persuasive because the reference indicates tTA in the presence of Tc is a DNA binding compound, which affects the binding of tTA (a transcriptional regulatory protein) to the DNA response element, thus, the reference anticipates the claims.

6. Claims 44 and 47-49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

7. Claims 40-43, 45, 46, 50, 51 and 54-59 are rejected, and claims 44 and 47-49 are objected to. It appears claims 52 and 53 are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner



May 11, 2004

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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